Complete Summary

GUIDELINE TITLE

Prevention and treatment of type 2 diabetes mellitus in children, with special emphasis on American Indian and Alaska Native children.

BIBLIOGRAPHIC SOURCE(S)

Gahagan S, Silverstein J. Prevention and treatment of type 2 diabetes mellitus in children, with special emphasis on American Indian and Alaska Native children. American Academy of Pediatrics Committee on Native American Child Health. Pediatrics 2003 Oct; 112(4):e328-e347. [137 references] PubMed

COMPLETE SUMMARY CONTENT

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES

SCOPE

DISEASE/CONDITION(S)

Childhood type 2 diabetes mellitus

IDENTIFYING INFORMATION AND AVAILABILITY

GUIDELINE CATEGORY

Diagnosis Management Prevention Treatment

CLINICAL SPECIALTY

Endocrinology
Family Practice
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses Dietitians Physician Assistants Physicians Social Workers

GUIDELINE OBJECTIVE(S)

- To improve the medical care for American Indian and Alaska Native (AI/AN) children with type 2 diabetes mellitus and those at risk of type 2 diabetes mellitus
- To support the role of the general pediatrician or other health care professional as the front line for care
- To serve as a framework for the development of diabetes care programs and strategies aimed at decreasing the devastating impact of type 2 diabetes mellitus on American Indian and Alaska Native children and their families and communities

TARGET POPULATION

All children, with special emphasis on American Indian and Alaska Native children with type 2 diabetes mellitus and those at risk of type 2 diabetes mellitus

INTERVENTIONS AND PRACTICES CONSIDERED

Prevention (primary and secondary) including community activities and clinically based primary and secondary prevention activities:

- 1. Patient and family education
- 2. Lifestyle behavioral changes
- 3. Early diagnosis and optimal medical care to prevent complications

Diagnosis

- 1. Population-based screening (only as part of research effort to advance knowledge about optimal prevention, diagnosis, and treatment)
- 2. Case finding
- 3. Clinic-based diagnosis including specialist consultations
- 4. History and psychological assessment
- 5. Physical assessment
- 6. Laboratory evaluation:
 - Fasting plasma glucose concentration test
 - Measurement of glycosylated hemoglobin (HbA_{1c}) concentration
 - Screening for proteinuria and/or microalbuminuria
 - Fasting lipid profile
 - Liver function tests

Note: C peptide and insulin concentrations were considered but should not be measured routinely.

Treatment

- 1. Patient, physician, and community education programs
- 2. Lifestyle modifications, including acquiring healthful behaviors in nutrition, exercise, and weight management
- 3. Self-monitoring of blood glucose
- 4. Preconception counseling and management
- 5. Hepatitis B, influenza, and pneumococcal immunizations
- 6. Dental examinations
- 7. Decreasing cardiovascular risk:
 - Treatment of hyperlipidemia with cholestyramine and colestipol hydrochloride
 - Blood pressure control with lifestyle changes and angiotensinconverting enzyme inhibitors
 - Smoking and alcohol cessation and prevention
 - Treatment of microalbuminuria
- 8. Pharmacologic management of type 2 diabetes
 - Subcutaneous insulin injections
 - Oral agents, such as metformin and sulfonylureas

Note: Metformin is the only oral hypoglycemic agent approved for use in children.

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVI DENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

The guideline developers reviewed published cost analyses.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Primary and Secondary Prevention

Prevention must take highest priority and should focus on decreasing the risk, incidence, and consequences of type 2 diabetes mellitus among American Indian/Alaska Native (AI/AN) children. Primary prevention efforts by primary health care professionals are recommended in 2 arenas: 1) general community health promotion and health education and 2) clinically based activities. Clinically based health promotion activities should not duplicate community-wide health promotion but instead should offer additive benefits. When type 2 diabetes mellitus is the established diagnosis, secondary prevention efforts by primary health care professionals are important for the prevention of complications (e.g., vascular, neural, renal, retinal). Early diagnosis and optimal medical care are the keys to effective secondary prevention.

To be effective, prevention efforts need a strong community base and acceptance. Current evidence suggests that modifiable risks for type 2 diabetes mellitus include obesity and lack of breastfeeding. Primary prevention efforts can focus on the prevention of obesity in children and the promotion of breastfeeding. Preventing obesity in women of childbearing age is another primary prevention

goal, because exposure to the environment of a diabetic pregnancy places the fetus at increased risk of future onset of diabetes.

Community Activities

Community prevention activities are being developed in AI/AN communities on the basis of each tribe's unique needs and resources. Development and implementation of these activities should have the endorsement of appropriate tribal authorities. Ideally, these activities are multidisciplinary (e.g., medical, nutrition, public health, nursing, health education) and include local businesses, community recreational programs, Head Start programs, and schools. Tribal food and nutrition programs (e.g., Special Supplemental Nutrition Program for Women, Infants, and Children; US Department of Agriculture's Food Distribution and Food Stamp program) have a prominent role in promoting foods that minimize the risk of obesity. Community programs and services should develop consistent messages and supply foods that assist in decreasing the prevalence of obesity. Studies to evaluate the effectiveness of community-based obesity and diabetes risk reduction efforts are in progress.

Pediatricians and other health care professionals should advocate for school policy that requires daily physical activity for every child and for physical fitness programs in the school and community. They should urge stores, restaurants, and schools to offer low-caloric density foods of high nutritional value in appropriate portions. Lack of physical activity is associated with the development of obesity, type 2 diabetes mellitus, and cardiovascular morbidity and mortality. Despite information on the importance of exercise, a low proportion of high school students participate in daily physical education classes. Increasing physical activity should include participating in at least 30 minutes of physical activity daily, limiting sedentary activity (e.g., watching television, playing video games, using a computer) to no more than 1 to 2 hours per day, and participating in sports. Community recreation programs and schools should encourage youth to participate in events that require physical activity. The community leadership should receive information on and understand the importance of physical activity and the value of having programs and facilities available for youth. Recommendations and programs should respect family, culture, and community values.

Clinically Based Primary and Secondary Prevention Activities

Health care professionals have influential roles in preventing type 2 diabetes mellitus among at-risk youth via direct patient care contacts. Children with 1 or more risk factors (see "Case Finding," below) identified by the American Diabetes Association (ADA) consensus panel on type 2 diabetes mellitus in children should be monitored closely. Identification of disorders associated with insulin resistance, such as acanthosis nigricans, polycystic ovarian syndrome (PCOS), and family history of diabetes, should trigger education and the initiation of prevention activities.

Children whose body mass index (BMI; see also "Physical Assessment," below) is greater than the 85th percentile for their age should receive appropriate counseling on nutrition, weight control, and physical activity. This is especially important because there is evidence that type 2 diabetes mellitus can be delayed

or prevented by lifestyle interventions. These children may require treatment for hypertension and hyperlipidemia and should return for follow-up evaluation and additional lifestyle intervention within 3 months.

Until results of current prevention trials with oral hypoglycemic agents in youth are available, intervention using glucose-lowering drugs for prevention of diabetes is not recommended. (These medications are, however, recommended for treatment of children with diagnosed type 2 diabetes mellitus.)

Knowledgeable health care professionals (e.g., nutritionists, health educators, physicians, nurses, community outreach workers) should guide nutrition interventions in AI/AN children and their families. Any intervention needs to consider growth and development in children. The most effective approach is appropriate reduction of calories along with increased energy expenditure. Specific recommendations need to be individualized, and continued evaluation is crucial for long-term success. Individualized plans are based on collaboration with the child and the family to assess food preferences, timing and location of meals and snacks, food preparation, and desire to change behaviors. Family resources and the availability of low-calorie nutritious foods in the community must be considered. Pharmacologic therapy to decrease weight is not recommended for children until more safety and efficacy data are available. Very low-calorie diets and high-protein diets are contraindicated, except in a well-controlled research setting. Quick-fix weight loss programs are unsafe for children and rarely result in long-term weight control; furthermore, they do not promote lasting, healthful eating behaviors. Weight loss programs with the best results combine exercise and dietary components with behavior modification. Accomplishing changes in the child's eating behavior and activity relies on changes made by the entire family.

<u>Identification</u>

Population-Based Screening

Many AI/AN communities are interested in population-based screening for type 2 diabetes mellitus. The evidence that microvascular complications of diabetes are strongly associated with previous hyperglycemia raises interest in earlier diagnosis during the asymptomatic period. However, population-based screening for type 2 diabetes mellitus in high-risk children is not recommended, except as part of research efforts to advance knowledge about optimal prevention, diagnosis, and treatment. Population-based screening remains controversial, because there are no data from controlled trials showing that earlier diagnosis improves long-term outcome. It is essential that studies be performed to determine the specificity, sensitivity, and cost-benefit of screening for type 2 diabetes mellitus in high-risk populations of children and adolescents.

The World Health Organization has recommended that before embarking on population-based screening, the following criteria be met:

- 1. The condition should be an important health problem.
- 2. There should be an accepted treatment for patients with recognized disease.
- 3. Facilities for diagnosis and treatment should be available.
- 4. There should be a recognizable latent or early symptomatic stage.
- 5. There should be a suitable test or examination.

- 6. The test should be acceptable to the population.
- 7. The natural history of the condition, including development from latent to declared disease, should be understood adequately.
- 8. There should be an agreed policy on whom to treat as patients.
- 9. The cost of case finding should be economically balanced in relation to possible expenditure on medical care as a whole.
- 10. Case finding should be a continuing process and not a once-and-for-all project.

Before beginning screening programs, health care systems and institutions must identify resources for intervention for people who will be identified with type 2 diabetes mellitus or altered glucose metabolism by the screening program. Screening programs can cause harm if effective treatment is not available.

Case Finding

Although population-based screening is not recommended, early case finding and early initiation of treatment may prevent some sequelae of type 2 diabetes mellitus. Overweight children who have entered puberty (or who are older than 10 years) are considered at risk by the ADA if they meet 2 of the following criteria:

- Family history of type 2 diabetes mellitus in first- or second-degree relative
- Race or ethnicity is American Indian, Alaska Native, Black, Hispanic, or Asian/Pacific Islander
- Presence of a condition associated with insulin resistance (acanthosis nigricans, hypertension, dyslipidemia, PCOS)

The following are definitions for being at risk for overweight:

- BMI between the 85th and 95th percentiles for age and sex
- Weight-for-height ratio between the 85th and 95th percentiles

The following are definitions for being overweight:

- BMI greater than the 95th percentile for age and sex
- Weight-for-height ratio greater than the 95th percentile
- Weight greater than 20% of the ideal weight for height

The term "obese" is not defined for children by the Centers for Disease Control And Prevention (CDC). Health care professionals should be knowledgeable about risk factors and make appropriate decisions to test individual patients.

Diagnosis (Clinic Based)

The diagnosis of type 2 diabetes mellitus in a child or an adolescent usually will be made by an astute health care professional in a clinical setting rather than as a result of a screening program. Knowledge of the aforementioned risk factors will assist the health care professional in considering and making the diagnosis when the patient is asymptomatic. Symptomatic and asymptomatic disease manifestations are described in "Pharmacologic Management on the Basis of Clinical Manifestations" (see below).

Specialists should be consulted for children and adolescents in whom diabetic ketoacidosis is detected. Furthermore, subspecialty consultation is indicated for children with hyperglycemia (fasting blood glucose [FBG] > 250 mg/dL [>13.9] mmol/L]) but without the clinical features, family history, or physical characteristics commonly associated with type 2 diabetes mellitus. In such cases, diagnostic differentiation between type 1 and type 2 diabetes mellitus may require additional studies, such as autoimmune markers (islet cell antibodies, glutamic acid decarboxylase antibodies), challenge tests with high-calorie nutritional supplements (e.g., Sustacal and Boost Nutritional Energy Drink [Mead Johnson Nutritionals, Evansville, IN]) or glucagon, or assays of insulin or C peptide. Children with type 2 diabetes mellitus may have normal or high C peptide and fasting insulin concentrations. However, children with type 2 diabetes mellitus with toxic effects of glucose attributable to prolonged hyperglycemia before diagnosis may have transient low insulin concentrations and may benefit from a short course of subcutaneous insulin therapy. Specialty consultation also should be sought when youth are unable to achieve treatment goals in a reasonable time frame or when complications occur. Specialty consultation is helpful for youth with hyperlipidemia and hypertension.

Ongoing Evaluation and Monitoring for Type 2 Diabetes Mellitus In Children

History and Psychosocial Assessment

A complete medical history, including a review of systems, is essential at diagnosis and at regular intervals (see Table 1 in the original guideline), with special attention to emotional disorders; eating disorders; alcohol, tobacco, and drug use; and family support. Emotional and behavioral disorders, particularly depression, have been associated with diabetes. Psychosocial assessment is recommended at diagnosis and informally at every visit. Assessment may be performed on the basis of patient history or by using a standardized screening tool. A social worker or a psychologist on the diabetes team can assist with this evaluation. If depression or another emotional disorder is identified, then treatment and referral should be initiated promptly.

Health care professionals and dietitians should screen for eating disorders as part of the standard nutrition evaluation for all children with type 2 diabetes mellitus. Binge eating and bulimia are significant concerns. Psychiatrically defined eating disorders are differentiated from culturally normal behaviors, some of which may be unhealthful.

The use of alcohol, tobacco, and drugs should be evaluated in all children and adolescents in whom diabetes is newly diagnosed, and it should be reevaluated, at least informally, at every visit. The family's attitudes toward the use of these and other substances should be evaluated as well. Alcohol use may aggravate hypoglycemia caused by sulfonylureas or insulin and increase the risk of lactic acidosis in patients who use metformin.

Family support is essential to the child or adolescent with type 2 diabetes mellitus. The family's strengths and needs should be assessed so that necessary assistance can be offered. This assessment should include positive and negative role models in the home, availability of healthful foods (e.g., fresh fruits and vegetables),

financial resources, parental literacy, cultural beliefs about health and illness, and the family's understanding of diabetes. The involvement of the whole family in dietary and activity changes will promote successful management of the child´s diabetes. A family history of diabetes and cardiovascular disease will influence the meaning of this illness within the family. Support services for the family may include health education, financial services, social services, mental health counseling, transportation, and home visiting. Socially disorganized families need early psychologic and social work intervention.

Physical Assessment

Although a complete physical examination is recommended for all children at diagnosis, special attention should be given to the elements provided in Table 2 in the original guideline.

Weight and height should be plotted on a growth chart. The weight goal should be based on BMI (weight [kg]/height² [m²]). (The Web site for growth charts is: www.cdc.gov/nchs/about/major/nhanes/growthcharts/charts.htm.) Weight should be measured at each visit, but height may be measured twice a year.

The blood pressure goal is less than the 90th percentile on the basis of height and weight standards. The blood pressure is assessed at each visit. Blood pressure control is discussed in "Reducing Cardiovascular Risk" (see below and Table 3 in the original guideline).

The skin, especially the back of the neck, the underarms, and the groin, should be evaluated for acanthosis nigricans, a thickened, hyperpigmented skin condition (see Figure 1 in the original guideline). Acanthosis nigricans often correlates with high BMI and insulin resistance. The resolution of acanthosis nigricans may be a useful marker for decreasing insulin resistance. Insulin resistance may improve as weight decreases. The improvement of the skin condition as a result of better metabolic control is highly desirable to adolescents. Therefore, identification of this condition is especially useful as a motivator for adolescents. Other treatable skin conditions may occur in association with insulin resistance, including tinea capitis, tinea corporis, and tinea pedis. Hirsutism or significant acne may be markers of hyperandrogenism in girls. Hirsutism is related to hyperinsulinism and is another potential motivating factor for adolescents to accomplish nutritional and physical activity goals.

A thorough visual inspection of the feet, including pedal pulses (posterior tibial and dorsalis pedis) and a neurologic examination are recommended shortly after diagnosis and then annually (see Figure 2 in the original guideline). The monofilament examination for foot sensation is included to assess protective sensation. This examination is performed using the 5.07 (10-g) Semmes-Weinstein nylon monofilament mounted on a holder that has been standardized to deliver a 10-g force when applied properly. Because the sensory deficits appear first in the most distal portions of the foot and progress proximally in a "stocking" distribution, the toes are the first areas to lose protective sensation. The examination should include assessment for treatable nail conditions, such as paronychia and ingrown toenails. The main purpose of the foot examination in children is to teach that foot care is an important health habit.

A funduscopic examination with dilation to detect signs of diabetic retinopathy is recommended shortly after diagnosis and then annually by an experienced eye care professional.

Yeast vaginitis and balanitis are commonly seen in children and adolescents with type 2 diabetes mellitus. Inspection of the vulva and penis should be included in the physical examination to screen for yeast vaginitis and balanitis. Tanner staging of children and adolescents with type 2 diabetes mellitus should be performed every 3 to 6 months until puberty is complete, because early onset of puberty is noted in overnourished children. A gynecologic examination for girls and a genital examination for boys may provide an opportunity to obtain additional sexual history and to offer abstinence and contraceptive counseling. Menstrual irregularities may be symptoms of PCOS in postpubertal girls.

Laboratory Evaluation

The fasting plasma glucose (FPG) concentration is the standard test for diagnosis. Monitoring is based on the FPG concentration and additional blood glucose measurements throughout the day. Fasting is defined as no consumption of food or any beverage other than water for at least 8 hours before testing. Most monitoring is performed by self-monitoring of blood glucose (SMBG) concentrations. Tables 4 and 5 in the original guideline include diagnostic and self-monitoring values.

The 2-hour postprandial glucose test provides information about glucose metabolism that is not provided by FPG measurement. It can be used for diagnosis together with FPG testing and must be used for monitoring.

Measurement of glycosylated hemoglobin (HbA_{1c}) concentration should be performed quarterly. The results should be available at the time of the patient visit and discussed with the patient. Many diabetes clinics have standing orders for the performance of HbA_{1c} testing before the health care professional's consultation and discussion with the patient. The HbA_{1c} result can verify SMBG data and is useful for identifying the need to adjust insulin dosage when SMBG data are unavailable. Setting realistic short- and long-term goals in consultation with a pediatric endocrinologist or other health care professional knowledgeable about childhood type 2 diabetes mellitus is recommended whenever possible. The HbA_{1c} concentration goal is less than 7.0% (or <1% above the laboratory reference range). This may not be achievable for all patients. Realistic goals should be individualized for each patient. HbA_{1c} concentration greater than 8.0% is associated with a substantial increase in complications. Any sustained decrease is beneficial.

It is important to screen for proteinuria at diagnosis and annually. Testing for microalbuminuria is indicated if proteinuria is absent. Microalbuminuria is a high urinary albumin concentration that is not detected on routine dipstick testing. Microalbuminuria is defined as a urinary albumin excretion of 20 to 200 micrograms per minute (30–300 mg per day). Annual screening for microalbuminuria permits early identification and treatment of patients who are at risk of nephropathy. The recommended method of detection is the measurement of the albumin-creatinine ratio in a spot urine collection. An alternative method uses reagent tablets or dipsticks that detect microalbuminuria. When positive, the

results of rapid tests should be confirmed by the urinary albumin-creatinine ratio in a timed urine collection. A patient is not designated as having microalbuminuria unless 2 of 3 collections performed within a 3- to 6-month period show increased concentrations. This test is not valid if the patient has a urinary tract infection or during menses. Although microalbuminuria may be encountered in patients in whom type 2 diabetes mellitus is newly diagnosed, proteinuria is the hallmark of diabetic nephropathy (Figure 3 in the original quideline).

The serum creatinine concentration should be determined at diagnosis and when indicated for drug therapy. Annual serum creatinine screening is indicated for patients with hypertension or microalbuminuria and for people taking angiotensin-converting enzyme (ACE) inhibitors.

A fasting lipid profile, including total cholesterol, low-density lipoprotein (LDL), high-density lipoprotein (HDL), and triglyceride concentrations, should be performed after diagnosis. The fasting lipid profile is best obtained after initial metabolic stabilization (1--3 months after diagnosis). The primary goal of therapy is to lower the LDL concentration, which is discussed further in "Reducing Cardiovascular Risk" (see below).

Liver function tests, including aspartate transaminase and alanine transaminase, should be performed before initiation of oral hypoglycemic therapy. Additional monitoring may be required depending on the person's drug regimen.

The concentrations of C peptide and insulin should not be measured routinely. When differentiation between type 1 and type 2 diabetes mellitus is difficult, consultation with a subspecialist with expertise in type 2 diabetes mellitus in children and adolescents is recommended. There currently is no definitive diagnostic tool to differentiate between type 1 and type 2 diabetes mellitus. The differentiation typically is made clinically on the basis of obesity, family history, ethnicity, age, pubertal status, and evidence of insulin resistance (e.g., acanthosis nigricans, PCOS).

Treatment

Goals of Treatment

The goals of treatment are adequate metabolic control (HbA_{1c} concentration <7%) and prevention of microvascular and macrovascular complications. More specific treatment objectives include the following:

- Eliminating symptoms of hyperglycemia
- Assisting the patient in maintaining a reasonable body weight (weight stabilization)
- Decreasing cardiovascular risk factors: hypertension, hyperlipidemia, hyperglycemia, microalbuminuria, sedentary lifestyle, and use of tobacco products
- Achieving overall improvement in the child's physical and emotional wellbeing

Recommended treatment modalities include dietary modification, increased physical activity, decreased sedentary behaviors, and pharmacologic intervention (primarily metformin and insulin). Therapy to achieve these goals should be individualized on the basis of the child's age, other illnesses, lifestyle, self-management skills, and level of motivation. Education and other interventions that enhance self-care behaviors are essential for the successful management of type 2 diabetes mellitus. In general, weight loss is not recommended for prepubertal children. Children with morbid obesity and resultant health consequences, such as sleep apnea, may be referred to a subspecialist for weight reduction or a multidisciplinary child obesity clinic. Weight stabilization is the goal until girls are menstruating and boys have reached Tanner stage 5. After pubertal growth is complete, weight loss may be appropriate.

Barriers to Care

Refer to the original guideline for a discussion of barriers to care, including barriers for AI/AN youth.

Team Management

Multidisciplinary team management is strongly recommended for youth with type 2 diabetes mellitus. A primary health care professional alone usually cannot provide focused diabetes education, nutrition management, and psychosocial support. The team usually is composed of a physician, a registered dietitian, a nurse clinician, a social worker, and the patient and the family. The patient and the family are integral members of the team, and participation of the child or adolescent with the diabetes team should be frequent and ongoing. The diabetes team monitors the patient's knowledge about diabetes and its acute and chronic complications. The team also assesses and monitors the patient 's knowledge and attitudes toward nutrition and physical activity. In addition, the team promotes the use of medications, SMBG, and problem-solving skills. Screening for barriers to self-care is recommended at each visit. The team assists in identification of achievable self-care goals that are appropriate for age and development level.

Many AI/AN health care facilities have existing diabetes clinics with multidisciplinary teams. It is highly recommended that these clinics organize a pediatric component so that youth receive developmentally appropriate care.

Lifestyle Modifications

The cornerstones of initial treatment of type 2 diabetes mellitus are acquiring and integrating healthful behaviors in nutrition, exercise, and weight management. Frequent contact with the health care team is required to accomplish these goals. The approach to healthful living must be emphasized throughout diabetes treatment. Initially, type 2 diabetes mellitus in asymptomatic youth may be managed by lifestyle modification without adjunctive medication. Basic diabetes education, counseling, and SMBG should be included. The natural history of type 2 diabetes mellitus is one of progressive insulin insufficiency and deterioration of metabolic control. Therefore, close monitoring and follow-up are important. Eventually, most people with type 2 diabetes mellitus require medication to achieve adequate metabolic control (Tables 4 and 5 in the original guideline).

Management Tools

Self-monitoring of Blood Glucose (SMBG)

The frequency of SMBG should be individualized. Daily fasting and 2-hour postprandial (after-dinner) glucose measurements are recommended. More frequent monitoring is recommended during initiation of treatment. Furthermore, monitoring frequency should be increased during the following situations: insulin treatment, medication dosage adjustments, initiation of new therapies, increased activity, rapid growth, illness, and emotional stress. The frequency of SMBG may be negotiated with the patient and the family. For people who take insulin, the recommended frequency of SMBG is before every meal and at bedtime. The recommended method is a blood glucose meter with memory. It can be instructive for patients to record their blood glucose results in a log to determine patterns. Reviewing these results with the patient at each visit is recommended. Many patients on medication will learn to make their own dosage adjustments on the basis of blood glucose patterns.

- Ideal targets: more than 50% of SMBG concentrations within target range:
 - Fasting: 80 to 120 mg/dL (4.4--6.7 mmol/L)
 - Postprandial (2 hours after start of meal): 100 to 160 mg/dL (5.6--8.9 mmol/L)
 - Bedtime: 100 to 160 mg/dL (5.6--8.9 mmol/L)

Medical Nutrition Therapy

Meal planning, nutrition education, and exercise are primary treatment strategies for type 2 diabetes mellitus. All people with diabetes should receive regular nutrition counseling and consult with a registered dietitian or nutritionist or a diabetes educator at least every 6 to 12 months. Some children may require more frequent evaluation and counseling. The success of the child in adopting healthful eating habits is much more likely when the entire family follows the dietary recommendations. Other family members may be able to serve as role models. Assisting the family and the patient in change related to eating behavior is recommended. For example, some families will choose to purchase more fruits and vegetables and make them more readily available to all family members. Families may choose to discourage eating outside of mealtimes and make rules about limiting eating while watching television. Weight management must be individualized for the patient initially and in follow-up visits. Each encounter is an opportunity for nutritional education.

Diabetes Education

Patients and their families require diabetes self-care information that is culturally relevant. It is important to recognize that there are many different tribal cultures. The National Standards for Diabetes Care and Patient Education provide guidelines for education program development with criteria specific for Native American health care facilities. In addition, adolescents have distinct needs related to the culture of youth.

Education alone is not enough to motivate people to adopt more healthful behaviors. Children and adolescents, in particular, are not easily motivated by

long-term health consequences, which seem irrelevant to them. They are more likely to be influenced by immediate concerns, such as physical attractiveness, feelings of well-being and acceptance, and their desire to be able to do more in school or sports. The use of motivational interviewing or collaborative problem solving may be useful in helping children and adolescents make and maintain necessary behavior changes.

Physical Activity Education

Physical activity is a cornerstone of the management of type 2 diabetes mellitus. Physical goals should be stated concretely. Exercise is associated with improvement in short- and long-term metabolic control, and physical activity improves insulin sensitivity. All patients should be assessed for level of fitness and current exercise routines. Recommendations should be based on the patient's needs and current condition. It is important to assess the opportunities available within the family and the community. Adaptive physical education classes may be helpful for children who are overweight. Youth with obesity and type 2 diabetes mellitus are not likely to participate in organized sports, so other physical activity strategies are needed. Activities of daily living can be adapted to increase physical fitness. Sedentary activities should be limited, and positive alternatives should be emphasized. When making behavioral changes, simple, achievable goals promote efficacy. Children and adolescents are more likely to accept fitness goals when they are framed in terms of feeling better, looking better, or doing more.

Preconception Counseling and Management

A sexual activity history should be obtained at diagnosis in postpubertal youth. Counseling about the necessity of metabolic control for healthful pregnancy outcomes should start at puberty. Abstinence counseling should be provided, if appropriate. Family planning options should be discussed with adolescents who are or may become sexually active. Pregnancy should be deferred until optimal glycemic control has been achieved to decrease first-trimester risks to the fetus, including congenital heart disease, caudal regression, and neural tube defects, and third-trimester risks of macrosomia, neonatal hypoglycemia, and hypocalcemia, all of which are common in preexisting type 2 diabetes mellitus and gestational diabetes. All oral hypoglycemic agents are contraindicated during pregnancy. Furthermore, treatment of diabetes may increase fertility and the likelihood of pregnancy in young women. Metformin, in particular, may improve ovarian function and ovulation.

Immunizations

Usual childhood immunizations (including hepatitis B, influenza, and pneumococcal immunizations) are recommended. Tuberculosis screening by purified protein derivative should be documented once after the diagnosis of diabetes and performed at appropriate intervals, as indicated by community-specific tuberculosis prevalence.

Dental Examinations

Dental examinations are recommended every 6 months. Periodontal disease is more common in people with diabetes than in those without and has been called

the sixth complication of diabetes (the other 5 complications involve the heart, kidney, eyes, skin, and feet).

<u>Decreasing Cardiovascular Risk</u>

Identification and Treatment of Hyperlipidemia

Children with type 2 diabetes mellitus are at risk of hyperlipidemia, which compounds their risk of premature cardiovascular disease. Although the American Heart Association recommends that children's total cholesterol concentration be less than 170 mg/dL (<4.40 mmol/L) and the LDL concentration be less than 110 mg/dL (<2.84 mmol/L), the ADA recommends a lower target concentration for LDL in adults with diabetes: less than 100 mg/dL (<2.59 mmol/L). Because of the higher risk of cardiovascular disease in children with diabetes, the lower acceptable value recommended by the ADA is preferred. A lipoprotein analysis after a 12-hour fast is recommended to obtain triglyceride concentrations for computation of accurate LDL concentrations. If a fasting measurement is not possible, then a measurement of the HDL concentration, along with the total cholesterol concentration, will provide an alternative. Other reliable analyses of the lipid profile may become available in the future. Children with an LDL concentration more than 100 mg/dL (>2.59 mmol/L) or a total cholesterol concentration more than 170 mg/dL (>4.40 mmol/L) should receive advice about other risk factors for cardiovascular disease, such as smoking and sedentary lifestyle. High triglyceride concentrations are increasingly recognized as an additional cardiovascular risk factor for people with diabetes. In addition to studies showing the benefit of decreasing the cholesterol concentration in adults, the Bogalusa Heart Study provides evidence that risk factors, such as a low HDL concentration, high triglyceride and LDL concentrations, and smoking, have clinical significance for development of cardiovascular disease beginning in childhood.

The American Heart Association Step-One diet should be initiated for children with high total cholesterol or LDL concentrations. The Step-One diet includes fewer than 30% of total calories from fat, fewer than 10% of total calories from saturated fat, 10% or fewer calories from polyunsaturated fat, and cholesterol of no more than 100 mg/1000 cal. If cholesterol concentrations do not normalize despite a history of adherence to the Step-One diet, then the Step-Two diet is used. For more information, access the American Heart Association's Internet site at http://www.americanheart.org/. The assistance of a registered dietitian or other qualified nutrition professional is necessary to ensure adequacy of nutrients, vitamins, and minerals. Glycemic control, as well as therapy with metformin, can help to lower triglyceride and LDL concentrations. Cholesterol-lowering drug therapy should be considered for children older than 10 years if an adequate trial of diet therapy is unsuccessful after 6 to 12 months. An LDL concentration of 100 mg/dL or more (≥2.59 mmol/L) and 1 of the following risk factors or physical inactivity indicate a need for cholesterol lowering medication: family history of premature cardiovascular disease (55 years or younger), cigarette smoking, high blood pressure, low HDL concentration (<35 mg/dL [<0.91 mmol/L]), and obesity $(\geq 95^{th}$ percentile weight for height).

The recommended cholesterol-lowering medications for children include cholestyramine and colestipol hydrochloride. These medications are difficult to

take because of the frequency of dosing and adverse gastrointestinal effects. Although the efficacy and safety of these medications have been documented in children, long-term data on improved morbidity and mortality are lacking.

Blood Pressure Control

In adults, tight blood pressure control has been shown to have a greater impact on cardiovascular disease risk reduction than blood glucose control. Systemic hypertension is defined as systolic or diastolic pressure greater than or equal to the 95th percentile for age. However, for children with type 2 diabetes mellitus, the blood pressure goal is less than the 90th percentile. Accurate blood pressure measurement is critical to the evaluation of suspected hypertension. The patient should be resting and comfortable. Cuff size, the position of the arm, the person's position (sitting or supine), and the speed of inflation and deflation of the cuff can affect the measurement. The cuff bladder width should be approximately 40% of the arm circumference midway between the olecranon and the acromion. The arm should be supported, and the cubital fossa should be at the level of the heart. The bell of the stethoscope should be placed over the brachial artery pulse. The cuff should be inflated to 20 mm Hg above the point at which the radial pulse disappears. The cuff is then deflated at a rate of 2 to 3 mm Hg per second. Automated devices are not as accurate for determining diastolic pressure. The diagnosis of hypertension should be confirmed in 3 separate consecutive examinations. For mild hypertension (slightly above the 95th percentile), the initial assessment should evaluate the possibility of renal disease. The evaluation of severe hypertension (>99th percentile for age) should include an echocardiogram.

Conservative management (e.g., lifestyle changes, such as weight decrease in postpubertal patients, nutrition, and exercise) is recommended as initial therapy. Sodium restriction may be difficult for adolescents. Significant reduction in blood pressure may be noted with weight loss and exercise programs. If blood pressure reduction is not achieved by lifestyle changes, then drug therapy will be necessary. Angiotensin-converting enzyme (ACE) inhibitors are the usual first-line agents because of cardiovascular and renal benefits. Because ACE inhibitors are teratogenic, another agent might be preferable for girls of childbearing age. Betablockers are an alternative unless the child is taking insulin, as symptoms of hypoglycemia may be masked.

Smoking and Alcohol Cessation and Prevention and Increasing Physical Activity

Smoking cessation and prevention of smoking initiation are essential for decreasing the risk of cardiovascular problems. Smoking is associated with an increased incidence of diabetes in adults. It is important to screen for tobacco use and advise or refer for tobacco cessation if use is confirmed. Tobacco use information should be updated at each visit. Because of the greatly increased risk of macrovascular and microvascular disease in people who have diabetes and smoke, children and adolescents who do not smoke or use other tobacco products should receive positive reinforcement and information about the importance of continued abstinence.

Alcohol use may aggravate the hypoglycemia caused by sulfonylureas or insulin treatment, and it may increase the risk of lactic acidosis for patients who use metformin. Alcohol and drug use should be assessed at every visit. Adolescents are at risk of substance abuse, which may interfere with the achievement of treatment goals. Anticipatory guidance regarding alcohol avoidance is recommended, including for children and adolescents who do not use alcohol or other drugs. The benefits of not drinking should be emphasized. The effectiveness of creative strategies should be evaluated.

Increasing physical activity is a positive way to decrease risk of cardiovascular complications.

Treatment of Microalbuminuria

Microalbuminuria is a sign of incipient diabetic nephropathy and is a risk factor for cardiovascular complications. Microalbuminuria may be encountered in people who have a new diagnosis of type 2 diabetes mellitus. Proteinuria, conversely, is the hallmark of diabetic nephropathy. ACE inhibitors are indicated for proteinuria or microalbuminuria and have been shown to slow the rate of progression of nephropathy in adults. Improved glycemic and blood pressure control slows the progression of nephropathy. ACE inhibitors are an additional important treatment modality, as shown in the evaluation and treatment algorithm (Figure 3 in the original guideline).

Pharmacologic Management on the Basis of Clinical Manifestations

The options for pharmacologic treatment include insulin; oral hypoglycemic agents, especially metformin; and any combination thereof. Intensive blood glucose control with insulin or sulfonylureas has been shown to decrease microvascular but not macrovascular complications. The choice of medications is discussed in relation to the patient's status at diagnosis. The following sections are given in order of increasing severity and decreasing incidence.

Impaired Glucose Metabolism

Patients with impaired glucose tolerance and impaired fasting glucose have glucose concentrations too high to be considered normal but do not meet the diagnostic criteria for diabetes. They are considered to have prediabetes. Patients with impaired fasting glucose have FPG concentrations of 110 mg/dL or more (\geq 6.1 mmol/L) but less than 126 mg/dL (<7.0 mmol/L). Patients with prediabetes have 2-hour oral glucose tolerance test (OGTT) results between 140 and 200 mg/dL (7.8 and 11.1 mmol/L [Table 5 in the original guideline]). Compared with the FPG, the 2-hour OGTT will identify more people as having impaired glucose tolerance. Although the 2-hour OGTT is more sensitive than the FPG, it is not as reproducible. It is, therefore, important to identify which test was used for diagnosis. An increase in the postprandial glucose concentration precedes an increase in the FPG concentration in adults. The natural history of impaired glucose tolerance in children and adolescents has not been studied. The United States Diabetes Prevention Program has shown that lifestyle interventions are more effective than metformin and both approaches are more promising than conventional treatment in reducing progression to diabetes in adults with impaired glucose tolerance. Similarly, a study of Finnish adults was interrupted because of

the success of the lifestyle intervention arm. Patients with prediabetes and their families should receive nutrition and physical activity intervention and support. Their risk of diabetes should be discussed. Monitoring of weight, nutrition, physical activity, and FPG should be performed regularly (at least every 3 months). Some diabetes centers recommend SMBG for high-risk patients with impaired glucose metabolism.

Asymptomatic Diabetes

People with diabetes may be identified as part of community-based case-finding efforts or by primary health care professionals who test asymptomatic children and youth who are at risk of type 2 diabetes mellitus. Patients with an FPG concentration of 126 mg/dL or more (\geq 7.0 mmol/L) or a 2-hour plasma glucose concentration of 200 mg/dL or more (\geq 11.1 mmol/L), using a glucose load of 75 g of anhydrous glucose dissolved in water, but who do not have polyuria, polydipsia, or weight loss are considered to have asymptomatic type 2 diabetes mellitus. When diabetes is identified early, treatment with lifestyle modifications and SMBG (fasting and postprandial) may be instituted. If plasma glucose or HbA_{1c} concentrations remain increased for 3 months, then treatment with oral agents or insulin should be started. Patients who attain euglycemia through lifestyle modification should be monitored every 3 months.

People with an FPG concentration greater than 250 mg/dL (>13.9 mmol/L) should be treated as if they have symptoms, even if they report none.

Symptomatic Diabetes Without Ketoacidosis

Symptoms include polyuria and polydipsia, nocturia, sleep apnea, vaginitis, dysuria, and even weight loss. Many families do not recognize polyuria and polydipsia in adolescents. Educational approaches to raise adolescent awareness about the potential significance of the symptoms of increased thirst and urination could encourage teenagers to alert their families and primary health care professionals.

Insulin

Initial treatment with subcutaneous insulin is suggested for children with FPG concentrations greater than 250 mg/dL (>13.9 mmol/L) and for children who are symptomatic. First Nations children with type 2 diabetes mellitus have been treated with subcutaneous insulin for 2 to 6 weeks followed by abrupt discontinuation of treatment with acceptable metabolic control.

The recommended starting dose of insulin is individualized from 0.5 to 1.0 U/kg body weight per day. Additional insulin may be given if blood glucose concentrations do not fall below 150 mg/dL (8.3 mmol/L) before meals. Insulin dosing must be adjusted on the basis of the blood glucose concentration. Children and adolescents with type 2 diabetes mellitus often require much higher doses of insulin because of insulin resistance. Insulin regimens must be individualized.

For more information on insulin refer to the original guideline.

Oral Agents

Metformin

The ADA consensus statement recommends that "if treatment goals with nutrition education and exercise are not met, pharmacologic therapy is indicated. The first oral agent should be metformin." Metformin works by decreasing hepatic glucose production and enhancing insulin sensitivity. It is contraindicated for people with renal or hepatic disease, conditions that lead to hypoxia (e.g., unstable asthma), or severe infection or those who abuse alcohol. It should be withheld before radiographic studies requiring the administration of radiocontrast dye. Metformin improves ovarian function, especially in women with PCOS, making family planning and contraception (when indicated) important.

Sulfonylureas

The primary mechanism of action of the sulfonylureas is enhancement of insulin secretion. In adults in whom type 2 diabetes mellitus has recently been diagnosed, good results have been achieved with mild to moderate fasting hyperglycemia (220–240 mg/dL [12.2–13.3 mmol/L]), good beta cell function as reflected by a high fasting C peptide concentration, and the absence of islet-cell or glutamic acid decarboxylase antibodies. No sulfonylureas are currently approved for use in children, although studies in the pediatric population with second-generation agents are ongoing. In most studies in adults, sulfonylureas have had neutral or slightly beneficial effects on plasma lipid concentrations. Weight gain is common with use, a negative effect in patients in whom weight loss is a major goal. Most pediatric endocrinologists use sulfonylureas with other agents when monotherapy with metformin or insulin sensitizers has failed. Table 6 in the original guideline outlines the pharmacologic characteristics of select sulfonylureas.

For more information on oral agents including repaglinide, thiazolidinediones, and acarbose, refer to the original guideline.

Combining Oral Agents

Because type 2 diabetes mellitus is a progressive disease with decreasing beta cell function, most people with an initial acceptable response to monotherapy will require additional agents as their disease progresses.

Because metformin promotes weight loss and decreases lipid concentrations, it is preferred for use by overweight people with type 2 diabetes mellitus and dyslipidemia. The dose of metformin or sulfonylureas can be increased over a 4-to 8-week period until acceptable glucose control is achieved or the maximum dose is reached. If monotherapy fails with metformin, then a sulfonylurea should be added. It is prudent to assess whether the person is taking the medication as directed before initiating combination therapy. Patients may not take their medication for a variety of reasons, including denial of illness; fear of being labeled diabetic; fear of adverse effects, such as hypoglycemia; actual adverse symptoms; and lack of knowledge about the need for long-term treatment. If combination therapy with 2 oral agents does not achieve the desired therapeutic goal, then bedtime insulin or a third oral agent may be considered. Referral to a

specialist in type 2 diabetes mellitus for children and adolescents is recommended when combination therapy has failed.

Symptomatic Diabetes with Ketoacidosis

Children with diabetic ketoacidosis require initial treatment with intravenous insulin followed by subcutaneous insulin. High doses may be required because of the insulin resistance characteristic of type 2 diabetes mellitus. Health care professionals, nurses, and laboratory professionals who care for a large number of patients with diabetic ketoacidosis are more likely to have the necessary clinical competence to provide this high-acuity care. When care by such personnel is not possible, consultation with a subspecialist is recommended. Excellent treatment protocols and guidelines are available for the treatment of ketoacidosis. Once the patient's condition is stable, the important lifestyle modifications discussed previously can be addressed. As people often are willing to consider major lifestyle changes during a crisis, this may be an optimal teachable moment.

CLINICAL ALGORITHM(S)

A clinical algorithm is provided in the original guideline document for annual evaluation and treatment for microalbuminuria.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting each recommendation is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

General Benefits

Appropriate medical care for American Indian and Alaska Native children with type 2 diabetes mellitus and those at risk of type 2 diabetes mellitus through education, prevention, and treatment

Specific Benefits

- Metformin. Advantages of metformin include decreased weight gain, possible weight loss, lower insulin concentrations, and improved lipid profile.
- Sulfonylureas. The second-generation sulfonylureas are largely free of drug interactions. The sulfonylureas have an additional advantage of low cost.

POTENTIAL HARMS

• Screening programs can cause harm if effective treatment is not available. Before beginning screening programs, health care systems and institutions must identify resources for intervention for people who will be identified with

- type 2 diabetes mellitus or altered glucose metabolism by the screening program.
- Lactic acidosis rarely has been associated with metformin. Gastrointestinal adverse effects, such as abdominal discomfort and diarrhea, occur in approximately 20 to 30% of people who take metformin.
- Sulfonylureas are commonly associated with weight gain. The major adverse effect associated with sulfonylureas is hypoglycemia. Other adverse effects are uncommon but include nausea; vomiting; and skin reactions, including rashes, purpura, and pruritus. Leukopenia, thrombocytopenia, hemolytic anemia, and cholestasis have been reported.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Very low-calorie diets and high-protein diets are contraindicated in children, except in a well-controlled research setting.
- All oral hypoglycemic agents are contraindicated during pregnancy.
- Metformin is contraindicated for people with renal or hepatic disease, conditions that lead to hypoxia (e.g., unstable asthma), or severe infection or those who abuse alcohol.
- Alcohol consumption is contraindicated when a person is taking a sulfonylurea.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The recommendations in this report do not indicate an exclusive course of treatment or serve as a standard of care. Variations, taking into account individual circumstances, may be appropriate.
- These guidelines have been developed to assist in clinical decision making by primary health care professionals and are not intended to replace existing management protocols for the medical treatment of diabetes.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT <u>CATEG</u>ORIES

IOM CARE NEED

Living with Illness Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Gahagan S, Silverstein J. Prevention and treatment of type 2 diabetes mellitus in children, with special emphasis on American Indian and Alaska Native children. American Academy of Pediatrics Committee on Native American Child Health. Pediatrics 2003 Oct; 112(4):e328-e347. [137 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

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GUIDFLINE STATUS

This is the current release of the guideline.

American Academy of Pediatrics (AAP) Policies are reviewed every 3 years by the authoring body, at which time a recommendation is made that the policy be retired, revised, or reaffirmed without change. Until the Board of Directors approves a revision or reaffirmation, or retires a statement, the current policy remains in effect.

GUIDELINE AVAILABILITY

Electronic copies: Available in from the <u>American Academy of Pediatrics (AAP)</u> <u>Web site</u>.

Print copies: Available from American Academy of Pediatrics, 141 Northwest Point Blvd., P.O. Box 927, Elk Grove Village, IL 60009-0927.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on February 20, 2004. The information was verified by the guideline developer on May 27, 2004.

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